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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,958	01/30/2007	William R. Jacobs JR.	96700/1031	2060
1912	7590	07/01/2010	EXAMINER	
AMSTER, ROTHSTEIN & EBENSTEIN LLP			SWARTZ, RODNEY P	
90 PARK AVENUE			ART UNIT	
NEW YORK, NY 10016			PAPER NUMBER	
			1645	
			MAIL DATE	
			DELIVERY MODE	
			07/01/2010	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/542,958

**Applicant(s)**

JACOBS ET AL.

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 5, 8, 10, 19, 41 and 87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 8, 10, 19, 41 and 87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 11 March 2010, is acknowledged. Claim 1 has been amended.
2. Claims 1, 5, 8, 10, 19, 41 and 87 are pending and under consideration.

#### **Rejections Maintained**

3. The rejection of claims 1, 5, 8, 10, 19, 41 and 87 under 35 U.S.C. 112, first paragraph, scope of enablement for a method for inoculating all mammals against *M. tuberculosis* utilizing an attenuated *M. tuberculosis* or *M. bovis* which has a deletion of RD1 and is auxotrophic for pantothenate, is maintained for reasons of record.

Applicants argue that the amendment of claim 1 to recite that the attenuated *M. tuberculosis* or *M. bovis* mycobacterium is administered in an "amount" "effective to confer protection against *M. tuberculosis* in the mammal" obviates the rejection. The argument is based upon the recital in Water et al that "Similar findings with cynomolgus monkey and neonatal calf trials, however, may be indicative of other, non-determined causes of vaccine failure such as inappropriate dose".

The examiner has considered applicants' argument, in view of the statement in Waters et al, but does not find it persuasive. The statement of Waters et al does not explicitly state that the failure of the trials using cynomolgus monkey and neonatal calf was due to inappropriate dose, but that the cause of the failure must be determined by further studies, as stated in the statement immediately prior to statement put forth by applicants.

Until such time as the further studies indicate that the only cause of the failure is due to inappropriate dosage, the evidence continues to support maintaining the rejection that the scope of enablement for a method for inoculating all mammals against *M. tuberculosis* utilizing

an attenuated *M. tuberculosis* or *M. bovis* which has a deletion of RD1 and is auxotrophic for pantothenate, is insufficient supported by the specification.

#### **Conclusion**

4. Claims 1, 5, 8, 10, 19, 41 and 87 are finally rejected.
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

July 1, 2010